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10/823,475	04/12/2004	Winthrop D. Childers	200309746-1	4580

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EXAMINER
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PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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08/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/823,475	<b>Applicant(s)</b> CHILDERS ET AL.	
	<b>Examiner</b> NIHIR PATEL	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on amendment filed on 05/03/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 21-36, 38-43 is/are pending in the application.
- 4a) Of the above claim(s) 29-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 21-28 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed on May 3<sup>rd</sup>, 2010 have been fully considered but they are not persuasive. The applicant argues that Lloyd does not disclose at least one selectively disabled resistor and disabling the resistor during a second maintenance mode. The examiner disagrees with the applicant's argument. Column 23 lines 9-16 and lines 21-28 recite "In order to produce a simple embodiment of the invention the microprocessor can be programmed within the above described ranges to release drug at the same point with respect to both inspiratory flow rate and inspiratory flow volume. This is desirable in that the microprocessor can than be programmed to allow a set amount of energy to be released to the formulation heater 13 and/or the air heater..." and "The drug delivery efficiency of the invention can be optimized by simultaneously or separately taking a variety of factors into consideration. For example, in addition to measuring (1) inspiratory flow rate and (2) inspiratory volume as described above one can optimize (3) particle size (4) drug concentration in the formulation (5) the amount of heat added..." , since the resistor 13/5 is controlled by the microprocessor it can inherently be disabled during a second maintenance mode and the fact that the drug delivery efficiency of the invention depends on the amount of heat added again inherently implies that the resistor is disabled during the second maintenance mode.

### ***Response to Amendment***

2. The examiner acknowledges the amendment filed on May 3<sup>rd</sup>, 2010. The amendment comprises amending claims 18 and 42.

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***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims **18, 19, 21, 26-28, 38, 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavis et al. (US 7,146,977) in view of Lloyd et al. (US 5,522,385).

6. **As to claim 18**, Beavis substantially discloses an apparatus that comprises a first pressurized supply of fluid in a reservoir **103** (see col. 2 lines 51-55 and col. 3 lines 20-25; the reference recites that “...For purposes of this application, the term aerosol includes airflows containing particles, such as aerosolized liquids, powders, and combination of two..” and the reference recites that “...For the purposes of the invention, the terms pressure, air flow and flow rate are all used interchangeably...” implies that the chamber **103** is pressurized as the phrase “airflow containing particles” implies); a fluid conduit **106** from the supply to an ejector head **111** (see fig. 1); a valve **105** operatively positioned in the fluid conduit between the supply and the ejector head (see fig. 1; col. 2 lines 64-67); a programmable

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controller (see col. 3 lines 24-40); wherein the reservoir 103, the fluid conduit 106, and the ejector head 111 form a fluidically connected fluid delivery unit controlled by the programmable controller 104 (see col. 2 lines 64-67); a first operational mode controlled by the controller; wherein, in the first operational mode of the fluid delivery unit, the ejector head is operable to deliver fluid from the reservoir through the ejector head, the fluid in the ejector head and the fluid conduit being at a lower pressure relative to the fluid in the reservoir (see col. 2 lines 60-67 and col. 3 lines 1-9); and a second maintenance mode controlled by the controller wherein, in the second maintenance mode of the fluid delivery unit, and the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the ejector head, the positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, and the positive pressure for the second maintenance mode being generated by opening the valve (see col. 3 lines 58-67 and col. 4 lines 1-19) but does not disclose at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode. Lloyd teaches an apparatus that does provide at least one selectively disabled resistor 13/5 and disabling the at least one selectively disabled resistor during the second maintenance mode (see col. 10 lines 8-18; **In Lloyd's reference the heating element is implemented only during delivery of the formulation inherently implying that the resistor 13/5 is disabled during the non-delivery state also second maintenance mode**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode as taught by Lloyd in order to heat the fluid during the delivery state so that the only material

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reaching the patient's is the substantially dry powder drug and disabled the resistor during the second maintenance mode blockage of the system, such as crystal growth and biological contamination that could result from fluid remaining otherwise remain within the conduit.

7. **As to claim 19**, Beavis substantially discloses an apparatus that comprises a pressure regulation apparatus in the reservoir to maintain the supply of fluid in a pressurized state (**see col. 2 lines 50-67 and col. 3 lines 1-15**).

8. **As to claim 21**, Beavis substantially discloses an apparatus that comprises a sensor means for monitoring an operational aspect of the ejector head (**see col. 2 lines 60-67 and col. 3 lines 15-25**).

9. **As to claim 26**, Beavis substantially discloses an apparatus that comprises a first pressurized supply of fluid in a reservoir **103** (**see col. 2 lines 51-55 and col. 3 lines 20-25**; the reference recites that "...For purposes of this application, the term aerosol includes airflows containing particles, such as aerosolized liquids, powders, and combination of two.." and the reference recites that "...For the purposes of the invention, the terms pressure, air flow and flow rate are all used interchangeably..." implies that the chamber **103** is pressurized as the phrase "airflow containing particles" implies); a fluid conduit **106** (**see fig. 1**) from the supply to an ejector head **111** (**see fig. 1**); a first valve **105** (**see fig. 1**) positioned in the fluid conduit between the supply and the ejector head; a programmable controller **104** (**see fig. 1**) capable of operating the delivery apparatus in a first operational mode wherein the ejector head is operable to deliver fluid from the supply through the ejector head (**see col. 2 lines 60-67 and col. 3 lines 1-15**), and in a second maintenance mode fluid is purged through the ejector head; a second pressurized supply of fluid in a reservoir **110** (**see fig. 1**; **col. 3**

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**lines 60-65);** a second fluid conduit from the second pressurized supply of fluid to the ejector head **(see fig. 1; the conduit connecting conduit 106 is defined as the second fluid conduit);** and a second valve **109 (see fig. 1; col. 3 lines 58-67)** positioned in the second fluid conduit but does not disclose at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode. Lloyd teaches an apparatus that does provide at least one selectively disabled resistor **13/5** and disabling the at least one selectively disabled resistor during the second maintenance mode **(see col. 10 lines 8-18; In Lloyd's reference the heating element is implemented only during delivery of the formulation inherently implying that the resistor 13/5 is disabled during the non-delivery state also second maintenance mode)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode as taught by Lloyd in order to heat the fluid during the delivery state so that the only material reaching the patient's is the substantially dry powder drug and disabled the resistor during the second maintenance mode blockage of the system, such as crystal growth and biological contamination that could result from fluid remaining otherwise remain within the conduit.

10. **As to claim 27,** Beavis substantially discloses an apparatus wherein the fluid in the first pressurized supply of fluid comprises a medication **(see col. 1 lines 43-55)**.

11. **As to claim 28,** Beavis substantially discloses an apparatus wherein the fluid in the second pressurized supply of fluid comprises a maintenance fluid **(see col. 3 lines 60-67 and col. 4 lines 1-20)**.

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12. As to **claim 38**, Beavis substantially discloses an apparatus that comprises an ejector head **111**; a pressurizable supply of fluid in a reservoir **103** (see **col. 2 lines 51-55 and col. 3 lines 20-25**; the reference recites that “...For purposes of this application, the term aerosol includes airflows containing particles, such as aerosolized liquids, powders, and combination of two..” and the reference recites that “...For the purposes of the invention, the terms pressure, air flow and flow rate are all used interchangeably...” implies that the chamber **103** is pressurized as the phrase “airflow containing particles” implies), the reservoir having a pressure regulation apparatus that supplies fluid to the ejector head at a controllable pressure (see **col. 2 lines 60-67 and col. 3 lines 1-15**); a fluid conduit **106** (see **fig. 1**) from the reservoir to the ejector head; a valve **105** (see **fig. ; col. 2 lines 60-67**) in the fluid conduit positioned between the reservoir and the ejector head (see **fig. 1**); and a control system **104** (see **fig. 1; col. 2 lines 60-67**); wherein the reservoir, the fluid conduit, and the ejector head form a fluidically connected fluid delivery unit controlled by the control system (see **col. 2 lines 60-67**), the control system being configured to control the fluid supply system in two different modes including (a) an operating mode wherein the fluid is supplied to the ejector head with an operational pressure such that the fluid in the ejector head and the fluid conduit are at a lower pressure relative to the fluid in the reservoir (see **col. 2 lines 60-67 and col. 3 lines 1-15**) and (b) an ejector head purge mode and the valve is opened to create positive pressure throughout the reservoir, the fluid conduit and the ejector head, the positive pressure purging out all remaining fluid from the fluid delivery unit by way of the disabled ejector head, the positive pressure for the ejector head purge mode being generated by opening the valve (see **col. 3 lines 58-67 and col. 4 lines 1-25**) but does not disclose at least one selectively disabled resistor and disabling the



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at least one selectively disabled resistor during the second maintenance mode. Lloyd teaches an apparatus that does provide at least one selectively disabled resistor **13/5** and disabling the at least one selectively disabled resistor during the second maintenance mode **(see col. 10 lines 8-18; In Lloyd's reference the heating element is implemented only during delivery of the formulation inherently implying that the resistor 13/5 is disabled during the non-delivery state also second maintenance mode)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode as taught by Lloyd in order to heat the fluid during the delivery state so that the only material reaching the patient's is the substantially dry powder drug and disabled the resistor during the second maintenance mode blockage of the system, such as crystal growth and biological contamination that could result from fluid remaining otherwise remain within the conduit.

13. **As to claim 42**, Beavis substantially discloses an apparatus that comprises an ejector head **111**; a fluid supply system having a pressure regulation apparatus that supplies fluid to the ejector head at a controllable pressure; and a control system configured to control the fluid supply system in two different modes including: (a) an operating mode wherein the fluid is supplied to the ejector head with an operational pressure **(see col. 2 lines 60-67 and col. 3 lines 1-15)**; and (b) an ejector head purge mode, and the fluid supply pressure is at a purge pressure that is different from the operational pressure; wherein the fluid supply system includes first and second fluids, and wherein the control system is configured for supplying the first fluid to the ejector head in the operating mode and the second fluid to the ejector head in the ejector head

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purge mode (**see col. 3 lines 58-67 and col. 4 lines 1-25**) but does not disclose at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode. Lloyd teaches an apparatus that does provide at least one selectively disabled resistor **13/5** and disabling the at least one selectively disabled resistor during the second maintenance mode (**see col. 10 lines 8-18; In Lloyd's reference the heating element is implemented only during delivery of the formulation inherently implying that the resistor 13/5 is disabled during the non-delivery state also second maintenance mode**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis's invention by providing at least one selectively disabled resistor and disabling the at least one selectively disabled resistor during the second maintenance mode as taught by Lloyd in order to heat the fluid during the delivery state so that the only material reaching the patient's is the substantially dry powder drug and disabled the resistor during the second maintenance mode blockage of the system, such as crystal growth and biological contamination that could result from fluid remaining otherwise remain within the conduit.

14. **As to claim 43**, Beavis substantially discloses an apparatus that comprises first fluid that comprises a medication and the second fluid comprises a maintenance fluid (**see col. 1 lines 40-45; col. 2 lines 50-60; and col. 3 lines 58-67**).

15. Claims **22-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavis et al. (US 7,146,977) in view of Lloyd et al. (US 5,522,385) further in view of Poole (US 6,158,431).

16. **As to claims 22 and 23**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable

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controller) for monitoring an operational aspect of the ejector head. Poole teaches an apparatus that does provide a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable controller) for monitoring an operational aspect of the ejector head (**see col. 12 lines 60-67**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd inventions by providing a sensor means (temperature sensor capable of measuring the temperature of a portion of the ejector head controlled by the programmable controller) for monitoring an operational aspect of the ejector head as taught by Poole in order to provide more accurate dose of medicament and to prevent the liquid from jamming the ejector head.

17. **As to claim 24**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a sensor means that comprises a counter for counting the number of times that the ejector head has been activated. Poole teaches an apparatus that does provide a sensor means that comprises a counter for counting the number of times that the ejector head has been activated (**see col. 13 lines 1-13**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd inventions by providing a sensor means that comprises a counter for counting the number of times that the ejector head has been activated as taught by Poole so that the user knows a head of time when to replace the pressurized fluid reservoir.

18. Claims **25 and 39-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beavis et al. (US 7,146,977) in view of Lloyd et al. (US 5,522,385) further in view of Koemer et al. (US 2004/0195352).

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19. **As to claim 25**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 18 above, but does not disclose a clock for measuring the time interval from a prior maintenance mode. Koerner teaches an apparatus that comprises a clock for measuring the time interval from a prior maintenance mode (**see paragraph [0023]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd inventions by providing a clock for measuring the time interval from a prior maintenance mode as taught by Koerner in order to provide medication to the patient at a proper time interval.

20. **As to claim 39**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the ejector head that includes thermal drop generators. Koerner discloses an apparatus wherein the ejector head includes thermal drop generators (**see figure 1; paragraph [00231]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd by providing an apparatus wherein the ejector head that includes thermal drop generators as taught by Koerner so that any liquid residues present evaporate and are discharged.

21. **As to claim 40**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the fluid at the operational pressure is at a negative gauge pressure. Koerner discloses an apparatus wherein the fluid at the operational pressure is at a negative gauge pressure (**see paragraph [00211]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd inventions by providing an apparatus wherein the fluid at the operational

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pressure is at a negative gauge pressure as taught by Koerner in order to provide medication to a patient with the correct amount of pressure.

22. **As to claim 41**, Beavis/Lloyd substantially discloses the claimed invention; see rejection of claim 38 above, but does not disclose an apparatus wherein the fluid at the purge pressure is at a positive gauge pressure. Koerner teaches an apparatus wherein the fluid at the purge pressure is at a positive gauge pressure (**see paragraph [0021]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Beavis/Lloyd inventions by providing an apparatus wherein the fluid at the purge pressure is at a positive gauge pressure as taught by Koerner in order to remove any residues remaining within the system.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772